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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/633,023

07/31/2003

H. Ernest Schnepf

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EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/633,023

Applicant(s)

SCHNEPF ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 26, 27 and 38-40 is/are pending in the application.
- 4a) Of the above claim(s) 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Application Status

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652.

2. Applicant's response to the Office Action mailed April 4, 2006 on September 11, 2006 is acknowledged.

Claim Disposition

3. Claims 1-2, 26-27 and 38-40 are pending. Claims 1-2 and 26-27 are under examination. Claims 38-40 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Newly added claims 38-40 are patentably distinct and would have been classified under class 435, subclass 69.1 and class 800, subclass 295; respectively. The above claims are not readable on the elected invention because the claims previously examined are drawn to a protein (class 530, subclass 350). Since the invention submitted in claims 38-40 are independent or distinct from the invention previously claimed for the reasons indicated above and since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Thus, claims 38-40 would have been subjected to a Restriction Requirement had they been presented at the time of filing.

Maintained and Amended-Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 1 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specific wash conditions of the claim appear to have no support in the specification. The Examiner has carefully reviewed the sections of the specification which were indicated as providing support for the amended claims & can find no mention of these conditions. At best, there is a citation of the Maniatis cloning manual, but no pages are indicated. Applicants have submitted two specific pages of that text, but the reference has not been made of record. Further, one might conjecture an improper incorporation by reference; however, these pages are directed to screening of bacterial colonies or bacteriophage plaques.

5. Claim 1 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nematicidal proteins encoded by SEQ ID NO:7, does not reasonably provide enablement for nematicidal proteins encoded by polynucleotides whose complement remains hybridized under the recited conditions to SEQ ID NO:7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to practice the invention commensurate in scope with these claims.. Applicants have obtained the specific protein of SEQ ID NO:8 but provided no teaching where one may reasonably expect to find other such proteins encompassed by the claims. The specification does not provide for the specific recited conditions. One has been given an invitation to experiment to try to find homologues of SEQ ID NO:8.

Maintained-Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-2, 26 and 27 remains rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6632792. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are directed to a toxin comprising SEQ ID NO:8 and a method of nematode control with the toxin; SEQ ID NO:8 is encoded by instant SEQ ID NO:7. Thus, the claims are directed to the same toxin.

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7. Claims 1-2, 26 and 27 remains rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 29-30, and 41-43 of U.S. Patent No. 4849217. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a specific δ -endotoxin encoded by SEQ ID NO:7 from PS-52A1, and a method of its use in killing nematodes, whereas the claims of the patent are directed to compositions selected from a group of cell lines, spores, toxins, and crystals from a large number of recited cell isolates including PS-52A1, and their use in a method of controlling insect infestations of alfalfa. The patent also recites claims to toxins active against the Egyptian alfalfa weevil produced by a large number of cell lines including PS-52A1. Absent evidence to the contrary, a method of controlling insect infestations of alfalfa is presumed to be unpatentable from a method of controlling nematodes, since the treatment method does not appear to be distinct (in the patented treatment method, it is presumed that nematodes in an alfalfa field would be controlled by the application method for alfalfa infestations). Likewise, with respect to the specific protein encoded by SEQ ID NO:7, it is presumed to be identical to the one claimed in the patent.

8. Claims 1-2, 26 and 27 remains rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 10, 13-14, 17, and 20 of U.S. Patent No. 4948734. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are directed to a process of controlling nematodes using an effective amount of a toxin produced by a *B.t* isolate, from a list of strains including pS-52A1. Absent evidence to the contrary, the patented process of

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controlling nematodes relies on the specific instant protein of SEQ ID NO:8, which is encoded by SEQ ID NO:7. The specific nematocidal toxin is deemed patentably indistinguishable from its use to control nematodes- the purified toxin is deemed obvious from its manner of use to control nematodes.

9. Claims 1-2, 26 and 27 remains rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5093120. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are directed to a process of controlling nematodes using an effective amount of a toxin produced by a *B.t* isolate, from a list of strains including pS-52A1. Absent evidence to the contrary, the patented process of controlling nematodes relies on the specific instant protein of SEQ ID NO:8, which is encoded by SEQ ID NO:7. The specific nematocidal toxin is deemed patentably indistinguishable from its use to control nematodes- the purified toxin is deemed obvious from its manner of use to control nematodes.

10. Claims 1-2, 26 and 27 remains rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5322932. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the patent is to a isolated toxin active against nematodes, which is encoded by a DNA sequence found in NM522 (pMYC2321). This DNA sequence encodes SEQ ID NO:8, and thus the claims are deemed patentably indistinguishable because the toxins

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are the same, even though the wording of the claims is not identical. A method of controlling nematodes using a nematicidal toxin is deemed an obvious use of the toxin.

Response to Applicant's Arguments:

11. Applicant's arguments have been fully considered including the Declarations presented by Dr. Ken Narva and Dr. Merlo. Note however, that the rejections of record remain for the reasons set forth above and herein. With regard to the written description and enablement rejections, applicant provide statements from Drs. Narva and Merlo, indicating that Example 5, Example 7 and pages 326-328 of Maniatis provide support for the hybridization conditions recited in the claims. These arguments are not persuasive. As stated above the claims recite a specific hybridization condition not found in the specification (thus not described or supported by the instant specification), and to point to Maniatis would result in an improper incorporation by reference. A skilled artisan is aware that hybridization conditions can vary especially the wash conditions. As the instant specification does not disclose the specific conditions recited in the claims, the claimed invention is neither adequately described or enabled for the full scope of the claims. Thus, the rejections of record remains because applicant did not delete the new matter introduced into the claims.

Regarding the Obvious-type double patenting rejections, applicant state that newly submitted claims 38-40 renders the rejections moot. This argument is not persuasive as the examined claims do not depend from the newly submitted claims. Furthermore, the newly

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submitted claims are withdrawn as directed to a non-elected invention. As applicant did not provide a Terminal Disclaimer, the rejections of record remains.

Conclusion

12. No claims are allowed.

13. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Primary Examiner

HR
1/13/07

HOPE ROBINSON
PRIMARY EXAMINER